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10/014,684	12/11/2001	Jonathan Caldwell Wright	3869/026	1015

7590

07/02/2003

Gottlieb, Rackman & Reisman, P.C.  
270 Madison Avenue  
New York, NY 10016-0601

EXAMINER

RADEMACHER, MARK A

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 07/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

**Office Action Summary**

Application No.

10/014,684

Applicant(s)

WRIGHT ET AL.

Examiner

Mark Rademacher

Art Unit

3761

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-72 and 80-100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-22, 28-35, 37-39, 45-52, 54-71, 80, 81, 87, 88 and 94-99 is/are rejected.
- 7) ☒ Claim(s) 23-27, 36, 40-44, 53, 72, 82-86, 89-93 and 100 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6, 8.                      6) ☐ Other:

Art Unit: 3761

## DETAILED ACTION

### *Election/Restrictions*

1. The applicant has canceled claims 1-19, 73-79 and 101-104 pursuant to 37 CFR 1.142(b); these claims being drawn to a nonelected invention(s), there being no allowable generic or linking claim. An election was made **without** traverse in Paper No. 9.
2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Priority*

3. The applicants' claim of domestic priority under 35 U.S.C. 119(e) is acknowledged.

### *Claim Objections*

4. Claims 58-60, 81, 82, 88, 89, 95, and 96 are objected to because the preambles and transition phrases of these claims are incongruent with the type and preamble of the base claim 80. For example, in claim 81 the applicant recites "[t]he apparatus of claim 80 further comprising the step of", which conveys to the reader that the applicant is claiming or modifying a method. However, the base claim is an apparatus claim. It appears that the applicant intended to recite "[t]he apparatus of claim 80 with further instructions for". Claims 82, 88, 89, 95 and 96 are objected to for the same reason as claim 81. Claims 58, 59 and 60 are objected to for the same incongruities. Appropriate correction is required. The applicant is also invited to review all of the claims and make similar corrections where appropriate.

*Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-22, 29, 30, 37-39, 46, 47, 54-63, 65, 66 and 94-99

6. Claims 20-22, 29, 30, 37-39, 46, 47, 54-63, 65 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent no. 5,704,345 to *Berthon-Jones*.

7. In FIG 2 *Berthon-Jones* discloses a CPAP apparatus that includes all of the features recited in the above claims including a computer programmed with instructions for controlling a blower to deliver breathable gas at a pressure above atmospheric to a patient and calculating a stroke indicator from a flow signal indicative of a patient's airflow.

8. *Berthon-Jones* discloses that the controller is programmed to calculate a number of indicators in the form of indexes that represent information about the patient's condition. For example, the controller calculates a "breathing index", which is compared to a set threshold to determine if a patient is experiencing apnea. The controller also calculates an "obstruction index", which, when compared to a set threshold, indicates the degree of obstructive apnea in the patient. In other words, the obstruction index is a function of obstructive apnea in the patient. Once apnea has been determined by calculation of a breathing index for example, the patency of the airway is determined by calculating a "patency index" or "leak-compensated patency index". The patency index(es) is a function of central apnea in a patient. See, e.g., FIGS 1, 16 and the accompanying discussion.

Art Unit: 3761

9. *Berton-Jones* further discloses that the apparatus includes instructions for identifying and delivering subsequent treatment based on one or more of the stroke indicators calculated. The subsequent treatment is a form of CPAP therapy. See, e.g., FIGS 1, 16 and the accompanying discussion.

10. With respect to the medium for storing instructions recited in claims 54-59, 65 and 66, it is the examiner's position that a recording medium having these instructions is inherent to a computer that performs the analysis recited therein. For example, the apparatus for analysis described by *Berthon-Jones* must include such a medium for storing instructions for performing the analysis disclosed because a computer/controller must utilize stored instructions in order to perform the analysis/calculations described.

11. Moreover, because the applicant has not positively recited a medium having instructions stored thereon, but instead merely functionally recites a "medium for storing instructions" any medium *capable* of storing the instructions meets the limitations of the claims. Accordingly, the apparatus disclosed by *Berthon-Jones* anticipates claims 60-63 and 94-99.

Claims 54-63, 80, 81, 87, 88 and 94-99

12. Claims 54-63, 80, 81, 87, 88 and 94-99 are rejected under 35 U.S.C. 102(b) as being anticipated by international publication no. WO 98/52467 to *Brydon*.

13. *Brydon* discloses all of the features recited in the above claims including a computer that processes a flow signal and that is programmed with instructions as recited. Specifically, the computer (system 101) delivers a breathable gas over a period of time, e.g., over night. The system measures the number of apneas and hypopneas per hour (i.e., the first index) and adjusts the pressure delivered to obtain a number of apneas and hypopneas per hour less than a threshold

Art Unit: 3761

number, e.g., 6 per hour. Forms of CPAP treatment (i.e., the ranges of pressures necessary to reduce the number of apneas and hypopneas per hour to below the threshold) are selected when the number of apneas and hypopneas exceeds the threshold. See, e.g., page 28, line 24 through page 29, line 30.

14. In addition, the system disclosed by *Brydon* includes instructions for querying for sleep history in the form of producing a report at the end of the diagnostic period that indicates physiological observations (e.g., movement and the like) that informs the choice of CPAP treatment. See, e.g., page 29, lines 25-30.

15. With respect to claims 94 and 95, it is the examiner's position that such a recording medium is inherent to a computer that performs the analysis recited therein. For example, the apparatus for analysis described by *Brydon* must include such a medium for storing having instructions for performing the analysis disclosed because a computer/controller must utilize stored instructions in order to perform the analysis/calculations described. The applicant should note that the examiner maintains the same position with respect to the remaining claims directed to a "recording medium".

16. Moreover, because the applicant has not positively recited a medium having instructions stored thereon, but instead merely functionally recites a "medium for storing instructions" any medium *capable* of storing the instructions meets the limitations of the claims. Accordingly, claims 94-99, as well as claims 54-63, are anticipated by the medium that must be part of the apparatus disclosed by *Brydon*.

***Claim Rejections - 35 USC § 103***

Art Unit: 3761

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28, 45 and 64

18. Claims 28, 45 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent no. 5,704,345 to *Berthon-Jones* in view of US patent no. 6,398,728 to *Bardy*.

19. *Berthon-Jones* disclose an apparatus including all of the features recited in claim 28, 45 and 64 without expressly disclosing an apparatus that includes a computer programmed with instructions for recording the stroke indicator in a database of stroke indicators for multiple patients.

20. However, such a feature was known at the time of invention. For example, US patent no. 6,398,728 to *Bardy* discloses an automated collection and analysis patient care system for diagnosing and monitoring respiratory insufficiency and outcomes thereof. The system includes a computer (18) that periodically records the physiological measures and records them in a database (17) of information for multiple patients. See, e.g., column 3, lines 40-51 and column 4, lines 43 through 51.

21. At the time of invention it would have been obvious to one with ordinary skill to modify the apparatus disclosed by *Berthon-Jones* to include instructions for recording the stroke indicator in a database of such information for multiple patients. One would have been motivated to do so in order to track and react to subtle trends and incremental changes in the

Art Unit: 3761

patient's health. See, e.g., *Bardy*, column 4, lines 43-52. In addition, one would have been motivated to do so in order to accumulate a large base of "knowledge" from which diagnostic and treatment evaluations may be made.

Claims 31-35, 48-52 and 67-71

22. Claims 31-35, 48-52 and 67-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent no. 5,704,345 to *Berthon-Jones* in view of published international application no. WO 98/50095 to *Burton*.

23. *Berthon-Jones* discloses a positive pressure apparatus including all of the features recited in claims 31-35 (and 48-52, 67-71) without expressly disclosing the processor including instructions for identifying a change in drug therapy based on the stroke indicator, evaluating changes in said stroke indicator to assess the efficacy of an administered drug and storing the stroke indicator in a database of patient information.

24. However, an apparatus that includes these instructions was known at the time of invention. For example, *Burton* discloses an apparatus for controlling drug delivery or gas to a patient. Specifically, a drug delivery module is controlled by a processor (5) to deliver drug therapy to a patient in accordance with physiological data collected from a patient and to determine the efficacy of the amount of drug delivered to the patient based on the detected physiological data. See, e.g., page 5, line 12 through page 6 line 2, and page 18, line 22 through page 19, line 14.

25. *Burton* also discloses that the apparatus can also store a monitored event type such as an apnea with its time and duration. Such stored information comprises a database. See, e.g., the discussion of "Step 8" beginning on page 19.



Art Unit: 3761

26. At the time of invention it would have been obvious to one with ordinary skill in the art to modify the *Berthon-Jones* apparatus to include the recited instructions for changes and evaluation of drug therapy and storage of the stroke indicator as taught by *Burton*. One would have been motivated to do so in order to be able to respond to a respiratory disorder that is not responsive to positive pressure therapy (see, e.g., *Burton*, page 5, lines 12-31) and to validate the information monitored by the apparatus (see, e.g., *Burton*, page 19, lines 22-29) for example.

***Allowable Subject Matter***

27. Claims 23-27, 36, 40-44, 53, 72, 82-86, 89-93 and 100 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten (i) in independent form including all of the limitations of the base claim and any intervening claims and (ii) to correct any objections raised in this action.

***Additional Pertinent Prior Art***

28. Although not relied upon, US patent no. 6,564,797 to *Mechlenburg et al* and the abstract titled "Investigating the Relationship Between Stroke and Obstructive Sleep Apnea" published by *Dyken et al* are considered pertinent to the applicant's disclosure.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Rademacher whose telephone number is (703) 305-0842. The examiner can normally be reached on Monday through Friday, 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the

Application/Control Number: 10/014,684

Page 9


Art Unit: 3761

organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MAR

June 25, 2003

  
GLENN K. DAWSON  
PRIMARY EXAMINER